K081237

SECTION 5 – 510(k) SUMMARY

AUG 25 2008

Submission Correspondent:	Emergo Group, Inc.
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Submission Sponsor:	Craftmaster Contour Equipment, Inc. PO Box 331345 Ft. Worth. TX 76163-1345 800.475.9260 817.568.9260 www.ccei.net
Date Prepared:	April 9, 2008
Trade Name(s):	1. Vista 2. Satellite Mobile Unit 3. Satellite Unit
Common/Usual Name(s):	Unit, Operative Dental (primary) Chair, Dental, With Operative Unit (secondary)
Classification Name(s):	Dental Operative Unit and Accessories (primary) Dental Chair and Accessories (secondary)
Classification Number(s):	872.6640 (primary) 872.6250 (secondary)
Classification Panel:	Dental Devices
CDRH Product Code:	EIA (primary) KLC (secondary)
Regulatory Class:	I

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Craftmaster Contour Equipment, Incorporated
C/o Mr. Stuart R. Goldmen
Senior Consultant
Emergo Group, Incorporated
1705 South Capital of Texas Highway
Suite 500
Austin, Texas 78746

AUG 25 2008

Re: K081237
Trade/Device Name: Vista
Satellite Mobile Unit
Satellite Unit
Regulation Number: 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: July 14, 2008
Received: July 15, 2008

Dear Mr. Goldmen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K081237

Device Name:

1. Vista
2. Satellite Mobile Unit
3. Satellite Unit

Indications for Use:

The CCEI Vista, Satellite Mobile Unit and Satellite Unit are dental operative units that are intended to supply utilities to and serve as a base for dental tools and accessories.

Prescription Use ____X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081237